REMARKS

Claim 22 has been canceled. No new claims have been added.

Claims 21, 23-24, and 37-47 are amended. These amendments are fully supported by the original claims and the specification as originally filed, for example for the purposes of illustration only, and not by means of any limitation, at page 10, lines 8-9 ("enabling longer useful lifetimes"); at page 15, lines 15-17 ("Pulsatile currents are typically characterized by the pulse amplitude, pulse frequency and the on/off percentage of time during the pulse frequency period"); and page 23, lines 15-16 ("FIGURE 3 illustrates components of one such circuit for the controlled delivery of pulsatile DC currents to electrodes"). As such, no new matter has been added.

Pending Claims 21, 23-27, and 37-47 are currently presented for examination.

Applicant thanks the Examiner for his review of the instant application. After having carefully considered the Office Action dated June 11, 2007, Applicant respectfully traverses the Examiner's claim rejections.

Rejections Under 35 U.S.C. § 112

The Examiner rejects Claims 21-27 and 37-47 under 35 U.S.C. 112, paragraph 2, as indefinite for combining two statutory classes. In particular, the Examiner asserts Claims 21-27 are directed to an apparatus, while Claims 37-47 are directed toward a method of using the device. Applicant thanks the Examiner for pointing out claim changes required to avoid the Examiner's 35 USC 112, paragraph 2 rejection. Claims have been amended in accordance with Examiner's suggestions, or in other ways, to avoid this rejection. For instance, Claim 46 now reads, "further comprises a biofluids sampling element."

The Examiner rejects Claim 21 as vague, as a device can not claim connection to a human body. Applicant thanks the Examiner for pointing out claim changes required to avoid the Examiner's rejection. Claim 21 has been amended to recite, "first surface adapted to contact tissue."

The Examiner rejects Claim 21 as incomplete for omitting an element to produce the time dependent signal. Claim 21 has been amended to positively recite a time dependent signal generator. The claim now recites, "a time dependent signal from a signal generator."

The Examiner rejects Claims 22-24 as vague in that the variation in surface charge has not been positively recited. Claim 22 has been presently canceled. Currently amended Claim 21, from which Claims 23 and 24 now depend, has been amended to positively recite the variation in surface charge. The claim now recites, "said surface charge being variable."

The Examiner rejects Claim 27 as vague, as no element has been set forth to deliver/produce/generate a variation or signal. Currently amended Claim 21, from which Claim 27 depends, has been amended to positively recite a time dependent signal generator. Claim 21 now includes "a time dependent signal from a signal generator."

The Examiner rejects Claim 37 as vague, as the claim does not further limit the parent claim. Applicant thanks the Examiner for pointing out claim changes required to avoid the Examiner's rejection. Claim 37 has been amended to recite, "wherein said device further comprises."

The Examiner rejects Claim 37 as incomplete, as there is no connection between the one or more first electrodes, the one or more second electrodes, the control circuitry and the device. Currently amended Claim 37 has been amended to recite, "wherein the control circuitry is coupled to both the first set of electrodes and the second set of electrodes."

The Examiner rejects Claim 37 as vague, as a device cannot claim connection to a human body. Applicant thanks the Examiner for pointing out claim changes required to avoid the Examiner's rejection. Claim 37 has been amended to recite, "adapted to be subdermally located."

The Examiner rejects Claim 37 as vague, as it is unclear if the electrodes are the same as the first tissue contacting surface or not. Applicant has amended Claim 37 to recite, "wherein the first tissue contacting surface comprises one or more first electrodes."

The Examiner rejects Claim 37 as vague, as it is unclear if the electrical current listed in lines 1-2 on page 3 of the claims is the same as the signal used in Claim 21. Applicant has amended Claim 37 to recite, "the electrical current results from the time dependent signal."

The Examiner rejects Claims 40 and 41 as incomplete, as there is no connection between the device and the electrodes that are affixed to the device. Applicant has amended Claims 40-41 to recite, "wherein one or more first electrodes is not affixed to the implanted portion of the

device." Thus, the device comprises one or more first electrodes. However, these electrodes are not affixed to the portion of the device which is implanted.

The Examiner rejects Claims 40 and 41 as vague, as it is unclear how the device communicates with the electrodes if they are not affixed to the device. Applicant has amended Claims 40-41 to recite, "wherein one or more first electrodes is not affixed to the implanted portion of the device." Accordingly, the medical device does communicate with the one or more first electrodes as recited in Claim 37, upon which Claims 40 and 41 depend.

The Examiner rejects Claim 42 as vague, as it is unclear what the applicant means by "percutaneous in nature." Applicant has amended Claim 42 to recite, "the device is adapted to be percutaneous."

The Examiner rejects Claim 43 as vague, as a device cannot claim connection to a human body. Applicant thanks the Examiner for pointing out claim changes required to avoid the Examiner's rejection. Applicant has amended Claim 43 to recite, "the device is adapted to be fully implanted."

The Examiner rejects Claim 44 as having an insufficient antecedent basis for the limitation "semipermeable structure." Applicant thanks the Examiner for pointing out claim changes required to avoid the Examiner's rejection. Applicant has amended Claim 44 to positively recite the semipermeable member element before it is used. Amended Claim 44 now reads, "wherein the device further comprises: a semipermeable structure."

The Examiner rejects Claim 45 as incomplete, as there is no connection between the therapeutic agent and the device. Applicant has amended Claim 45 to recite "wherein the device further comprises a therapeutic agent delivery element."

The Examiner rejects Claim 46 as incomplete, as there is no connection between the sampling fluids and the device. Applicant has amended Claim 46 to recite "wherein the device is further comprises a biofluids sampling element."

In view of the foregoing remarks, Applicant respectfully requests that the Examiner withdraw the rejections of any claims under 35 U.S.C. § 112.

Rejections Under 35 U.S.C. § 102

Rejections in Office Action Paragraph 25

The Examiner rejects Claims 21, 25-27, 37-43 and 45-57 under 35 U.S.C. 102(e) as being anticipated by Kroll et a'. (US Pat. No. 7,203,550, hereinafter "Kroll"). The Examiner asserts that Kroll discloses an implantable device with an electric current for fighting infection, working in conjunction with antibiotics.

Applicant has amended independent Claim 21 to include the limitations of original Claim 22 and now positively recites "wherein said variation guides the migration of selected cell types to produce a longer useful lifetime of the device by limiting undesirable cellular responses to foreign bodies." The combination of these characteristics is not present in the Kroll reference. Kroll does not discuss migration of any cells in response to the electric currents, nor does Kroll discuss limiting undesirable cellular responses to foreign bodies.

Because of this, Applicant respectfully submits that Kroll does not teach every element of presently amended independent Claim 21 and Claims 25-27, 37-43 and 45-57, dependent thereon. Accordingly, Kroll does not anticipate the inventions defined by these claims.

Rejections in Office Action Paragraph 26

The Examiner rejects Claims 22-24 under 35 U.S.C. 102(e) as being anticipated by Kroll. The Examiner asserts that Kroll teaches an implantable device with an electric current for fighting infection. The Examiner acknowledges that Kroll fails to disclose that cells are migrated and that those cells are endothelial or fibroblast cells. Instead, the Examiner states that Kroll discloses a current density that is the same as the current density disclosed in the application, so that it is inherent that the Kroll invention would cause cell migration since the values are similar and would cause migration of both endothelial and fibroblast cells. The Examiner notes that this variation has not been positively recited.

Applicant respectfully submits that the system described by Kroll does not inherently possess the property of inducing certain cell type migrations to produce a longer useful lifetime of the device by limiting undesirable cellular responses to foreign bodies. "The fact that a certain

result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic." *M.P.E.P.* § 2112, Sec. IV, 8th Ed., Rev. 5 (citing *In re Rijckaert*, 9 F.3d 1531, 1534, emphasis in original). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference.' " *Id.* (quoting *In re Robertson*, 169 F.3d 743, 745, emphasis added). Indeed, "[i]n relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Id.* (quoting *Ex parte Levy*, 17 USPQ2d 1461, 1464, emphasis in original).

Applicant respectfully submits that presently amended independent Claim 21, and accordingly Claims 23-27 and Claims 37-47 which depend thereon, is not anticipated by Kroll under the doctrine of inherency. The Kroll invention is directed to treat an infection in the surrounding biofilm of an implanted cardiac device. Kroll, col. 2, lines 1-3. Kroll describes the biofilm as a conglomerate of microbial organisms imbedded in a highly hydrated matrix of exopolymers. *Id.*, col. 1, lines 48-49.

Kroll describes using an average current density of 150 microamperes per square centimeter to be therapeutic. *Id.*, col. 9, lines 48-52. Kroll notes that an electric current applied at that density could interfere with the heart's conduction, thereby pacing the heart or inducing an arrhythmia. *Id.*, col. 9, lines 52-55. To avoid this, the duration of the electrical current varies according to the heart's refractory period or in a frequency range which is too rapid to affect the heart. *Id.*, col. 9, lines 22-27. For example, Kroll describes using electrical currents pulsed at a relatively slow rate, e.g., with a duration of greater than 10 ms but less than approximately 300 ms to be applied based on timing of the cardiac cycle. *Id.*, col. 10, lines 27-57. In another example, Kroll describes using electrical currents pulsed at a relatively rapid rate, e.g. with a frequency of approximately 1-10kHz, which is too rapid to be "felt" by the heart cells. *Id.*, col. 10, lines 61-64. With such operation, bacteria residing in a biofilm on the treatment device are destroyed. *Id.*, col. 9, lines 45-58.

In contrast to Kroll, the Applicant's invention relates to minimizing fibrous capsule formation and enhancing the useful lifetime of the medical device. The electric currents are

employed as a means for mobilizing or directing biomaterials (typically proteins and modified proteins, or certain cell types) toward or away from critical device locations, surfaces and surrounding areas. In certain embodiments of the invention, the electric currents are pulsatile in nature, pulsed at a frequency generally between 0.1 and 1000 Hz. Specification, page 13, lines 21-23. By pulsing the electric current in this way, charged signaling peptides, proteins, or certain cell types such as fibroblasts, macrophages, mast cells, etc., will be physically moved or directed from the critical device locations. Furthermore, under these conditions, not only are biomaterials mobilized or directed, but detrimental side effects associated with the process of running an electrical current through a solution (e.g. pH effects, electrolysis effects, gas generation, etc.) are reduced as well. Specification, page 12, line 20 – page 13, line 4.

Applicant has amended independent Claim 21 to positively recite "wherein said variation guides the migration of selected cell types to produce a longer useful lifetime of the device by limiting undesirable cellular responses to foreign bodies." Applicant respectfully submits that the combination of these characteristics are not inherent in the Kroll reference. Kroll makes no mention of the migration of certain cell types. The reference only discusses the destruction of a biofilm as a result of an electric current. Even if the electric field variations in Kroll cause some migration of cells, this does not establish the inherency of all the limitations of amended Claim 21. Claim 21 requires the production of variable surface charges that are sufficient to enhance device lifetime through significant cellular migration of appropriate cell types at appropriate times. This is not inherent in Kroll.

Accordingly, Applicant respectfully submits that Koll does not anticipate the inventions defined by Claims 23-24.

Rejections in Office Action Paragraph 27-29

The Examiner further rejects Claims 40-42 and 46 under 35 U.S.C. 102(e) as being anticipated by Kroll.

As discussed, Applicant has amended Claim 21, upon which Claims 40-42 and 46 depend, to recite "variation guides the migration of selected cell types to produce a longer useful lifetime of the device by limiting undesirable cellular responses to foreign bodies." For at least

the same reasons discussed above, Applicant respectfully submits that because Kroll does not discuss guiding the migration of selected cell types, the reference does not teach or inherently include every element of the amended independent Claim 21 upon which Claims 40-42 and 46 depend. As such Kroll does not anticipate the inventions defined by these claims.

Applicant respectfully requests that the Examiner withdraw the rejections of any claims under 35 U.S.C. § 102.

Rejections Under 35 U.S.C. § 103

The Examiner has rejected Claim 44 under 35 U.S.C. 103(a) as being unpatentable over Kroll.

The Examiner acknowledges that Kroll does not teach an electrode being separated from tissue by a semipermeable layer. For this limitation, the Examiner states that it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device, because it was known in the art that lead electrodes covered in a semipermeable layer of an antibiotic provide direct placement of an antibiotic near implantation sites to fight infection. Applicant has not seen this characteristic disclosed in the references cited, and requests additional clarification as to the teaching and definition of "electrodes covered in a semipermeable layer of an antibiotic." Specifically Applicant respectfully requests the Examiner provide a reference or other evidence, in order to be evaluate the facts on which the conclusion of obviousness was reached. See, M.P.E.P. § 2142, 8th Ed., Rev. 5 ("the prior art reference (or references when combined) must teach or suggest all the claim limitations")

Notwithstanding the above, Applicant has presently amended Claim 21, upon which Claim 44 depends, to recite "wherein said variation guides the migration of selected cell types and enables a longer useful lifetime of the device." For at least the same reasons discussed previously, Applicant respectfully submits that the combination of these characteristics is not present or suggest in Kroll. As such Kroll does not render obvious the inventions defined by these claims.

Accordingly Applicant respectfully requests that the Examiner withdraw the rejections of any claims under 35 U.S.C. § 103(a).

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: 11/9/07

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